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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,999	03/23/2006	Veronique Barberousse	11123.0105USWO	9044

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EXAMINER	
HENRY, MICHAEL C	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,999	BARBEROUSSE ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 03/23/06 & 07/18/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the phrase "A compound according to claim 1, wherein the compound is utilized for the preparation of a drug". However, the claim is indefinite because, it is unclear how the claimed compound can be utilized in the preparation of a drug and still remain the same claimed compound according to claim 1 (as opposed to a different composition such as pharmaceutical composition). Also, it is unclear whether the compound is used to prepare a new drug (such as by a chemical modification or reaction).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A written description analysis involves three principle factors:

(1) field of the invention

(2) breath of the claims, and

(3) possession of the claimed invention at the time of filing for each claimed species/genus based upon the teachings of the specificaiton and the field of the invention.

The Federal Circuit court stated that written description of an invention "requires a precise definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to distinguish it from other material". University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed Cir. 1997). The court also stated "Naming a type of material generally known to exist, in the absence as to what the material consists of is not a definition of that material". Id. Further, the court stated that to adequately describe a claimed genus, adequate must describe a representative number of species of the claimed genus, and that one skilled in the art should be able to "visualize or recognize the identity of the members of the genus". Id .

(A) Provide a brief backdrop of the field of the invention. A reference from the BACKGROUND might very well be sufficient.

(B) Outline the scope and content of the claims briefly

(C) At the time of filing, from the disclosure, does it appear applicants were indeed in possession of the claimed invention?

The claims are drawn to a compound according to claim 1, wherein the compound is utilized for the preparation of a drug intended for the prevention or treatment of thromboses, especially venous thromboses. The examiner notes that the knowledge and level of skill in this art would not permit one skilled in this art to prepare a drug to prevent thromboses and the skilled artisan could not immediately envisage the invention claimed. Applicant claims are drawn to a compound according to claim 1, wherein the compound is utilized for the preparation of a drug intended for the prevention or treatment of thromboses, especially venous thromboses, which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies a drug wherein the said compound is utilized that can prevent the said disease or condition, which is seen to be lacking a clear description via art recognized procedural and methodological steps. First, it must be noted that there are two distinct forms of thrombosis: venous and arterial. There are several different forms of venous thrombosis include deep venous throbosis, portal vein thrombosis, hepatic vein thrombosis (Budd-Chiari syndrome), Paget-Schroetter disease and cerebral venous sinus thrombosis. The different form of arterial thrombosis includes stroke, a myocardial infraction (usually coronary thrombosis due to rupture of an atherosclerotic plaque) and thoracic outlet syndrome (may precipitate arterial thrombosis as well as venous). In addition, the prevention of such disease(s) or condition(s) does not have a single recognized cause. For example, it is known that thrombosis is caused by abnormalities in the composition of the blood (hypercoagulability), the quality of the vessel wall (endothelial cell injury), the nature of the blood flow (hemostasis) and slow nerve action. In fact, the aforementioned disease or condition, is recognized as having

many contributing factors, ranging from hereditary considerations, to lifestyles choices such as the diet and maintenance of bodily healthiness and includes factors such as an injury to the vessel's wall (such as by trauma, infection, or turbulent flow at bifurcations), the slowing or stagnation of blood flow past the point of injury (which may occur after long periods of sendentary behavior, a blood state of hypercoagulability (caused for example, by genetic deficiencies or autoimmune disorders) and family history of stroke or heart disease. These are only a few of the factors that promote these diseases in people. Applicant has not provided a description as to how any cause (like the aforementioned) can be prevented, much less a description of how a drug wherein the said compound is utilized can prevent the said disease(s) or condition (s). Furthermore, Applicant has not provided any clear description via art recognized procedural and methodological steps. Moreover, Applicant has not provided an adequate representation of the mode of treatment of said disease(s) or condition (s) to provide a full, clear and precise indication that applicant is in possession of the members of the methodological and procedural steps which would enable the skilled artisan to practice this invention by said diseases.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 10, 11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-13, 17 of copending Application No. 11/909,489. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are directed to thioxylose compounds of a given formula.

The difference between applicant's claimed compound and the compound of Barberousse et al. is the type of substituents on the pyridine ring of the compound of formula 1. Therefore, it is obvious to a skilled artisan to alter the substituents (such as the alkylsulfonylamino to the alkylsulfonyl) on the pyridine ring of Barberousse et al.'s compound so as to produce different derivatives with the same utility.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have altered the substituents on the pyridine ring of Barberousse et al.'s compound so as to produce different derivatives, in order to use them to treat venous thrombosis.

One having ordinary skill in the art would have been motivated, to alter the substituents on the pyridine ring of Barberousse et al.'s compound so as to produce different derivatives, in order to use them to treat venous thrombosis.

Claims 8-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-16 of copending Application No. 11/909,489. Although the conflicting claims are not identical, they are not

patentably distinct from each other because both inventions are directed to a process for the manufacture of a compound according to claim 1.

The difference between applicant's claimed process and the process of Barberousse et al. is the type of substituents on the pyridine ring of the compound of formula 1. Therefore, it is obvious to a skilled artisan to use the process of Barberousse et al. and to alter the substituents (such as the alkylsulfonylamino to the alkylsulfonyl) on the pyridine ring of Barberousse et al.'s compound so as to produce different derivatives with the same utility.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have altered the substituents on the pyridine ring of Barberousse et al.'s compound so as to produce different derivatives, in order to use them to treat venous thrombosis.

One having ordinary skill in the art would have been motivated, to alter the substituents on the pyridine ring of Barberousse et al.'s compound so as to produce different derivatives, in order to use them to treat venous thrombosis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

11/24/07

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

November 17, 2007.